

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
SHERMAN DIVISION

GLEND A MCCOY, and JOHN ROBERT  
MCCOY, themselves as PLAINTIFFS, and on  
behalf of decedents JON ANDREA ROBERTS,  
MICAYLA ROBERTS AND DYLAN  
ROBERTS,

Plaintiff,

v.

PFIZER, INC, and GREENSTONE  
PHARMACEUTICALS, LLC,

Defendant.

Civil Action No. 4:09cv496

JUDGE: MICHAEL H. SCHNEIDER

**DEFENDANTS' REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT**

## **INTRODUCTION**

Defendants' summary judgment motion showed that Defendants are entitled to summary judgment because (i) Plaintiffs cannot establish causation as required by settled Texas law, and (ii) Plaintiffs cannot establish that the sertraline warning was inadequate, or that a different warning would have prevented their alleged injuries. Plaintiffs' opposition fails, most importantly, because Plaintiffs fail to adduce competent evidence rebutting the extensive evidence adduced by Defendants demonstrating their entitlement to summary judgment. Additionally, Plaintiffs present numerous erroneous legal arguments, as shown below.

## **ARGUMENT**

### **I. PLAINTIFFS FAIL TO COME FORWARD WITH ANY COMPETENT SUMMARY JUDGMENT EVIDENCE**

Plaintiffs failed to adduce any evidence establishing the existence of a material factual dispute, much less competent summary judgment evidence. Plaintiffs responded to Defendants' "Statement of Undisputed Material Facts" by reciting, *verbatim* and without citation to evidence, the allegations of their Complaint. (*Compare* Dkt. 77 at ¶¶ 7-47 to Dkt 100 at § III ("Response to Statement of Material Fact").) "[M]ere conclusory allegations are not competent summary judgment evidence, and such allegations are insufficient . . . to defeat a motion for summary judgment." *Eason v. Thaler*, 73 F.3d 1322, 1325 (5th Cir. 1996). By reciting the allegations of their Complaint long after discovery has closed, Plaintiffs have essentially conceded that they cannot prove their claims at trial. This failure independently justifies entry of summary judgment for Defendants. *See Versai Mgmt. Corp. v. Clarendon Am. Ins. Co.*, 597 F.3d 729, 735 (5th Cir. 2010) (Rule 56 requires entry of judgment "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that

party will bear the burden of proof at trial.” (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)).<sup>1</sup>

## **II. PLAINTIFFS’ FAILURE TO ADDUCE SCIENTIFIC EVIDENCE OF GENERAL CAUSATION REQUIRES SUMMARY JUDGMENT FOR DEFENDANTS**

In *Havner* and *Garza*, the Texas Supreme Court has held that in the absence of direct causation evidence, a plaintiff must present at least two reliable epidemiological studies finding a statistically significant doubling of risk of the outcome at issue to establish a material issue of general causation for trial. *See Merrell Dow Pharmaceuticals, Inc. v. Havner*, 953 S.W.2d 706, 717 (Tex. 1997); *Merck & Co., Inc. v. Garza*, 347 S.W.3d 256 (Tex. 2011). It is undisputed that Plaintiffs’ sole causation expert, Dr. Glass, did not base his opinions on evidence sufficient to meet the *Havner/Garza* standard. (*See* Dkt. 94-9 (Glass Dep. at 148:5-11; 237:12-17).)

In their response brief, Plaintiffs concede, as they must, that Dr. Glass did not rely on two reliable epidemiological studies finding a statistically significant doubling of risk of the outcome at issue. (Dkt. 100 at 18-19.) However, they wrongly assert that *Havner/Garza* set forth only an admissibility standard for epidemiological studies, and that they can prove general causation without meeting this standard. On both scores, Plaintiffs are wrong.

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<sup>1</sup> Plaintiffs’ response also runs afoul of this Court’s local rules, which require that a response to the moving party’s “Statement of Undisputed Material Facts,” “be supported by appropriate citations to proper summary judgment evidence.” LOCAL RULE CV-56(b). “Proper summary judgment evidence means excerpted copies of pleadings, depositions, documents, electronically stored information, answers to interrogatories, admissions, affidavits or declarations, stipulations . . . , and other admissible evidence.” LOCAL RULE CV-56(d). Because the Court will “assume that the facts as claimed and supported by admissible evidence by the moving party are admitted to exist without controversy, except to the extent that such facts are controverted in the response filed in opposition to the motion, as supported by proper summary judgment evidence,” and Plaintiffs failed to support the facts they purport to controvert with any evidence, this Court should assume all of Defendants’ claimed facts as true. LOCAL RULE CV-56(c).

First, Plaintiffs' contention that *Havner* is a procedural, rather than substantive, requirement is belied by *Havner* itself, which held that reliability and sufficiency are inextricably linked, such that if an "expert's scientific testimony is unreliable" it is "legally, no evidence." *Havner*, 953 S.W.2d at 714.<sup>2</sup> Moreover, Plaintiffs fail to explain how Dr. Glass's causation opinion is "scientifically reliable" under *any* standard when he could not identify any epidemiological study of sertraline that purports to have found any increased risk, much less a statistically significant doubling of risk, for either suicide or homicide in adult patients. (Dkt. 94-9, (Glass Dep. at 148:5-11; 237:12-17).) Lacking such studies, Dr. Glass admittedly relies instead on uncontrolled, anecdotal case reports. (*Id.* at 160:16-23.) As *Havner* explicitly held, however, such anecdotal reports are insufficient to meet Plaintiffs' burden to establish causation. 953 S.W.2d 706, at 720.

Second, Plaintiffs' contention that they can establish "other evidence of general causation" via the sertraline package insert is nothing short of absurd. As Defendants showed in their Opening Brief, the sertraline package insert states that "short term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24." (Dkt. 94 at 5.) This document plainly cannot meet the *Havner/Garza* standard to establish that sertraline causes suicide in adults. Further, Plaintiffs attempt to manufacture a triable issue of fact by claiming Ms. Roberts' prescribing physician's testimony "seemed to imply that he was

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<sup>2</sup> Additionally, Defendants cited numerous cases holding *Havner* to constitute a substantive requirement of Texas law in their opening brief. (Dkt. 94 at 15-16.)

aware that akathisia was another possible side effect”<sup>3</sup> of Zoloft and asserting—without citation to any evidence—that Zoloft “can and does . . . cause extremely dangerous side effects” should be rejected. (Dkt. 100 at 20.) Dr. Glaser was asked whether he was aware that “anxiety, agitation, panic attacks . . . and akathisia . . . have been reported in adult and pediatric patients being treated with antidepressant” before 2004, to which he responded, “I don’t know.” (Dkt. 100-2 (Dep. of Dr. Glaser) at 40:4-15 (incorrectly identified in Plaintiffs’ response as Dep. of Dr. Glaser 38/10-19). This response does not “imply” Dr. Glaser was aware of the risk of akathisia. Plaintiffs’ purported litany of “extremely dangerous side effects” and conclusory allegation that “Defendants have also known for many years that Zoloft can induce akathisia” should be similarly disregarded because it is not supported by competent evidence. (Dkt. 100 at 20.) More importantly, even if these facts had any credence, the “seeming implication of awareness of a side effect” by Dr. Glaser would not suffice to establish causation under *Havner/Garza*.

### **III. THE LEARNED INTERMEDIARY DOCTRINE DEFEATS EACH OF PLAINTIFFS’ INADEQUATE WARNING CLAIMS**

#### **A. There is Insufficient Evidence to Apply the *Centocor* Exception to the Learned Intermediary Doctrine**

Relying on a Texas Court of Appeals case, which is currently on appeal to the Texas Supreme Court, Plaintiffs contend that the learned intermediary doctrine does not apply because “Defendants directly advertised to patients like Andrea Roberts in a misleading fashion.” (Dkt. 100 at 23 (citing *Centocor, Inc. v. Hamilton*, 310 S.W.3d 476 (Tex. App. 2010), *pet. granted*).

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<sup>3</sup> Plaintiffs’ repeated references to akathisia are puzzling, considering that their expert Dr. Glass, conceded that there is no evidence Ms. Roberts experienced akathisia. (Glass Dep. at 165:8-13, excerpt attached as Ex. 1.)

Because Plaintiffs fail to present evidence that would support *Centocor's* exception to the learned intermediary doctrine, this argument fails.<sup>4</sup>

First, Plaintiffs contend that *Centocor's* exception to the learned intermediary doctrine should apply because “Defendants aggressively distributed and marketed Zoloft, encouraging all types of physicians[, including Ms. Roberts’ physician] to dispense and prescribe Zoloft.” (Dkt. 100 at 24-25.) As their evidentiary support for this contention, however, Plaintiffs cite only an article appearing in *Forbes* magazine in 1999 and several Youtube videos. Neither source constitutes competent summary judgment evidence, and thus Plaintiffs are left with no evidence relating to Defendants’ marketing of Zoloft. Second, unlike the plaintiff in *Centocor*, who watched the purportedly misleading marketing video, there is no evidence that Ms. Roberts saw any advertisement or marketing for Zoloft or that any alleged “misleading” statements in those materials influenced her decision to take Zoloft in any way. *See Centocor*, 310 S.W.3d 476, at 511 (plaintiff “saw the video during her first infusion prescribed by Dr. Hauptman” and “testified that after watching the video, she ‘felt good about Remicade treatment’”). Third, and importantly, it is undisputed that Ms. Roberts was dispensed generic sertraline manufactured by Defendant Greenstone, and not Zoloft manufactured by Defendant Pfizer. (Dkt. 94 at ¶¶ 22-23.) Plaintiffs offer no evidence (because there is none) that Greenstone ever marketed sertraline to consumers.

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<sup>4</sup> Because Plaintiffs fail to present evidence that would support the exception announced in *Centocor*, it is not necessary for this Court to reach the question of whether the Texas Supreme Court will adopt *Centocor's* exception to the learned intermediary doctrine.

**B. Plaintiffs Fail to Adduce Competent Evidence to Rebut the Presumption That the Warning Was Adequate**

Plaintiffs assert that they can rebut the presumption of the label's adequacy with evidence that the FDA was misled. Once again, Plaintiffs fail to offer competent summary judgment evidence in support of their contention. (*See* Dkt. 100 at 26-29.) Plaintiffs' conclusory allegations cannot defeat summary judgment. Additionally, as Defendants showed in their Opening Brief, expert testimony would be necessary to establish a labeling defect. (Dkt. 94 at 22-24.) Plaintiffs offer no evidence or argument demonstrating how they can establish such a defect without expert testimony, and their warning claim fails for this reason as well.

**C. There is No Evidence That Dr. Glaser Would Not Have Prescribed Zoloft Had the Warning Been Different**

Defendants' Opening Brief showed that Dr. Glaser still would view Ms. Roberts as an appropriate candidate for sertraline based on everything he knows today. (Dkt. 94 at 22-24.) Plaintiffs have offered no evidence to refute this fact. Instead, they offer the speculation that "it is not a stretch that a jury would find that had he been adequately informed and privy to all of the available findings, Dr. Glaser would not have prescribed Zoloft (Sertraline) to Andrea Roberts." (Dkt. 100 at 30.) But Plaintiffs must do much more than establish that "it would not be a stretch" that a jury might reach a conclusion contrary to the facts—they must present competent evidence to rebut Defendants' showing. This they fail to do. Defendants are, accordingly, entitled to summary judgment on this ground, as well.

**CONCLUSION**

For the reasons set forth in Defendants' motion and above, summary judgment should be entered for Defendants on all of Plaintiffs' claims.

Dated: January 19, 2012

Respectfully submitted,

s/ Andrew Myers

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**CERTIFICATE OF SERVICE (CM/ECF)**

I HEREBY CERTIFY that a true and correct copy of defendants' **DEFENDANTS' REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT** was served via manner indicated below this 19<sup>th</sup> day of January, 2012 to the following:

|                             |   |
|-----------------------------|---|
| Thomas M. Corea, Esq.       | <input type="checkbox"/> First Class Mail                               |
| Jessica S. Graham, Esq.     | <input type="checkbox"/> Hand Delivery                                  |
| The Corea Firm PLLC         | <input type="checkbox"/> Facsimile                                      |
| The Renaissance Tower       | <input type="checkbox"/> Overnight Delivery                             |
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| Dallas, TX 75270            |   |
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*Attorneys for Plaintiffs*

s/ Andrew Myers

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